TABLE VI-continued

SAPROPTERIN DIHYDROCHLORIDE DRUG PRODUCT
(300-MG TABLET, 45 TABLET BOTTLES)
STORAGE CONDITIONS: 25 ± 2° C./60 ± 5% RH

	Stability	Time point (months)		
Test/Assay	Specification	0	3	6
Disintegration	≦3 minutes	2 min 57 sec	2 min 3 sec	2 min 50 sec
HPLC Assay	90-110%	102%	NT	103%
HPLC for Related Substances	≦0.1% individual unidentified	0.06%	NT	0.08% (RRT 0.56) 0.04% (RRT 0.61) 0.05% (RRT 0.65) 0.04% (RRT 0.81)
	≦0.5% total unidentified	0.15%	NT	0.21%
	≦2.0% total related substances	0.15%	NT	0.21%
	Report Result (mg/tablet)	5	NT	5
	Total Aerobic Microbial Count ≦ 1000 cfu/g	<100 cfu/g	NR	NR
	Test for *Escherichia coli* = absent	Absent		

ND = None detected
NT = Not tested
NR = Not required

TABLE VII

SAPROPTERIN DIHYDROCHLORIDE DRUG PRODUCT
(300-MG TABLET, 45-TABLET BOTTLES)
STORAGE CONDITIONS: 40 ± 2° C./75 ± 5% RH

	Stability	Time Point (months)		
Test/Assay	Specification	0	3	6
Appearance by Visual Inspection	White to light yellow compressed tablets	Conforms	Conforms	Conforms
Loss on Drying	Report Result	0.7%	1.1%	1.1%
Disintegration	≦3 minutes	2 min 57 sec	2 min 41 sec	2 min 48 sec
HPLC Assay	90-110%	102%	NT	101%
HPLC for Related Substances	≦0.1% individual unidentified	0.06%	NT	0.13% (RRT 0.56) 0.03% (RRT 0.61) 0.10% (RRT 0.65) 0.04% (RRT 0.81)
	≦0.5% total unidentified	0.15%	NT	0.30%
	≦2.0% total related substances	0.15%	NT	0.30%
	Report Result (mg/tablet)	5	NT	5

ND = None detected
NT = Not tested
NR = Not required

What is claimed is:

1. A formulation, comprising about 100 mg of crystal form B of (6R)-L-erythro-tetrahydrobiopterin dihydrochloride and about 5 mg of ascorbic acid in the form of a tablet.

2. The formulation of claim **1**, further comprising crospovidone, dibasic calcium phosphate, D-mannitol, riboflavin and sodium stearyl fumarate.

3. The formulation of claim **1**, further comprising crospovidone.

4. The formulation of claim **1**, further comprising dibasic calcium phosphate.

5. The formulation of claim **1**, further comprising D-mannitol.

6. The formulation of claim **1**, further comprising riboflavin.

7. The formulation of claim **1**, further comprising sodium stearyl fumarate.

8. A formulation, comprising crystal form B of (6R)-L-erythro-tetrahydrobiopterin dihydrochloride and ascorbic acid in the form of a tablet, wherein the weight ratio of ascorbic acid to (6R)-L-erythro-tetrahydrobiopterin is about 1:5.5, about 1:6, about 1:6.5, about 1:7, about 1:7.5, about 1:8, about 1:8.5, about 1:9, about 1:9.5, about 1:10, about 1:10.5, about 1:11, about 1:11.5, about 1:12, about 1:12.5, about 1:13, about 1:13.5, about 1:14, about 1:14.5, about 1:15, about 1:15.5, about 1:16, about 1:16.5, about 1:17, about 1:17.5, about 1:18, about 1:18.5, about 1:19, about 1:19.5, about 1:20, about 1:20.5, about 1:21, about 1:21.5, about 1:22, about 1:22.5, about 1:23, about 1:23.5, about 1:24, about 1:24.5, about 1:25, about 1:25.5, about 1:26, about 1:26.5, about 1:27, about 1:27.5, about 1:28, about 1:28.5, about 1:29, or about 1:29.5.

9. The formulation of claim **8**, further comprising crospovidone, dibasic calcium phosphate, D-mannitol, riboflavin and sodium stearyl fumarate.

10. The formulation of claim **8**, further comprising crospovidone.

11. The formulation of claim **8**, further comprising dibasic calcium phosphate.

12. The formulation of claim **8**, further comprising D-mannitol.

13. The formulation of claim **8**, further comprising riboflavin.

14. The formulation of claim **8**, further comprising sodium stearyl fumarate.

15. The formulation of claim **8**, wherein the weight ratio of ascorbic acid to (6R)-L-erythro-tetrahydrobiopterin is about 1:16.5, about 1:17, about 1:17.5, about 1:18, about 1:18.5, about 1:19, about 1:19.5, about 1:20, about 1:20.5, about 1:21, about 1:21.5, about 1:22, about 1:22.5, about 1:23, about 1:23.5, about 1:24, about 1:24.5, or about 1:25.

16. The formulation of claim **8**, wherein the weight ratio of ascorbic acid to (6R)-L-erythro-tetrahydrobiopterin is about 1:19, about 1:19.5, or about 1:20.

17. A formulation, comprising crystal form B of (6R)-L-erythro-tetrahydrobiopterin dihydrochloride and ascorbic acid in the form of a tablet, wherein the weight ratio of ascorbic acid to (6R)-L-erythro-tetrahydrobiopterin is about 1:2, about 1:3, about 1:4, or about 1:5.

18. The formulation of claim **17**, further comprising crospovidone.

19. The formulation of claim **17**, further comprising dibasic calcium phosphate.

20. The formulation of claim **17**, further comprising D-mannitol.

21. The formulation of claim **17**, further comprising riboflavin.

22. The formulation of claim **17**, further comprising sodium stearyl fumarate.

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